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RVD2009-01

## Re-evaluation Decision

# Maleic Hydrazide

*(publié aussi en français)*

**12 January 2009**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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**Canada**

ISBN: 978-1-100-11193-3 (978-1-100-11194-0)

Catalogue number: H113-28/2009-1E (H113-28/2009-1E-PDF)

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## Overview

### Re-evaluation Decision

After a re-evaluation of the plant growth regulator maleic hydrazide, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing maleic hydrazide for sale and use in Canada.

An evaluation of available scientific information found that products containing maleic hydrazide do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of maleic hydrazide uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of maleic hydrazide was first presented in Proposed Re-evaluation Decision PRVD2008-24, *Maleic Hydrazide*, a consultation document.<sup>1</sup> This Re-evaluation Decision<sup>2</sup> describes this stage of PMRA's regulatory process for the re-evaluation of maleic hydrazide as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-24. To comply with this decision, registrants of products containing maleic hydrazide will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

### What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Maleic hydrazide, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision that requires appropriate risk-reduction measures for Canadian uses of maleic hydrazide. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated maleic hydrazide and published its conclusions in a 1994 RED. In addition, the USEPA published a Tolerance Reassessment Eligibility Decision (TRED) in 2005 for maleic hydrazide, which included an aggregate risk assessment.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-24, *Maleic Hydrazide*.

## **What Is Maleic Hydrazide?**

Maleic hydrazide is a plant growth regulator applied in the field to control sprouting of potatoes and onions while in storage or to grass and trees to limit their growth (e.g. along the edges of residential lawns in hard-to-mow areas, along highways, airport property, industrial areas, golf course roughs). Maleic hydrazide can be applied by air or by ground equipment, by farm workers and by professional (custom) applicators.

## **Health Considerations**

### **Can Approved Uses of Maleic Hydrazide Affect Human Health?**

**Maleic hydrazide is unlikely to affect your health when used according to the revised label directions.**

Exposure to maleic hydrazide may occur through diet (food and water), working as a mixer/loader/applicator or by entering treated sites prematurely. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that the reregistration of maleic hydrazide was acceptable provided risk-reduction measures to further protect workers were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

### Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Maleic hydrazide is currently registered in Canada for use on potato and onion and could be used in other countries on crops that are imported into Canada. MRLs of maleic hydrazide are established for the following commodities:

- 50 ppm on potatoes;
- 15 ppm on onions; and
- 30 ppm on beets, carrots and rutabagas.

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

## Environmental Considerations

### What Happens When Maleic Hydrazide Is Introduced Into the Environment?

**Maleic hydrazide is unlikely to affect non-target organisms when used according to the revised label directions.**

Non-target organisms, including terrestrial plants, birds, mammals and non-vascular aquatic plants, could be exposed to maleic hydrazide in the environment. Environmental risk is assessed by the risk-quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of maleic hydrazide was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require terrestrial buffer zones for maleic hydrazide to protect terrestrial plants from spray drift.

## **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of maleic hydrazide, the PMRA is requiring further risk-reduction measures for product labels.

### **Human Health**

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers entering treated sites prematurely

### **Environment**

- Additional advisory label statements to reduce potential surface water and groundwater contamination
- Buffer zones to protect non-target, sensitive terrestrial habitats

Appendix I lists all required label amendments.

## **Other Information**

Any person may file a notice of objection<sup>3</sup> regarding this decision on maleic hydrazide within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, [www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html](http://www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html)), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail ([pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca)).

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Appendix I      **Label Amendments for Products Containing Maleic Hydrazide**

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

- I)      The following statements must be included in the **PRECAUTIONS** section.

Wear a long-sleeved shirt, long pants, shoes and socks during mixing, loading, application, cleanup and repair for all methods of application. In addition, wear chemical-resistant gloves during mixing/loading and when applying by hand-held equipment.

Wear a dust mask during mixing/loading activities.

- II)      The following statements must be included in the **DIRECTIONS FOR USE** section.

DO NOT enter or allow worker entry into treated areas for 12 hours following application.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wingspan or rotorspan.



### Buffer Zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelterbelts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:
			Terrestrial Habitat
Field sprayer	Potato, onion (sprout inhibition)		1
	Tree/shrub, non-crop grass (growth control)		
Airblast	Tree/shrub (early season)		10
Aerial	Onion	Fixed or rotary wing	15
	Potato	Fixed or rotary wing	20

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

- III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

**TOXIC** to non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposing of wastes.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay).



Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

